CERTIFICATE OF EXPRESS MAIL

NUMBER <u>EL 831792425 U5</u> DATE OF DEPOSIT <u>OCTOBER 22, 2003</u>

I hereby certify that this paper or fee is being deposited with the United States Postal Service "EXPRESS MAIL POST OFFICE TO ADDRESSEE" service under 37 C.F.R. 1.10 on the date indicated above and is addressed to: MS Patent Application, Commissioner for Patents, P.O. Box 1450 Alexandria, VA 22313-1450.

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Daniel N. HEINTZ Yunhau N. JENG

Serial No.: To be assigned

Filed: Herewith

For: NON-AQUEOUS INJECTABLE

FORMULATION PREPARATION WITH

pH ADJUSTED FOR EXTENDED RELEASE OF SOMATOTROPIN

Group Art Unit: To be assigned

Examiner: To be assigned

Atty. Dkt. No.: 11916.0046.DVUS02

PRELIMINARY REMARKS

MS Patent Application

Commissioner for Patents P.O. Box 1450 Alexandria VA, 22313-1450

Sir:

This paper provides Applicant's Preliminary Remarks in the above captioned application, which is filed concurrently herewith.

I. **Changes from Parent Application**

Pursuant to the provisions of 37 C.F.R. §§ 1.51, 1.53, and 1.63 (d) the enclosed Specification has been modified from the parent document (i.e. application number 09/894,058) as indicated below. Unless otherwise indicate all page numbering refers to the parent application, *i.e.* No. 09/894,058). Applicant believes that no new matter is entered by these modifications.

A. The paragraph at page 2, line 1, has been amended as follows:

"This is a divisional application of copending application Serial No. 09/894,058, filed June 28, 2001, that claims [priority to] the benefit of Provisional Application Serial No. 60/215, 599 filed June 30, 2000."

B. The original claims have be replaced with new claims 1-22.

II. Rational and support for changes

Applicant notes that the Specification filed herewith is modified with respect to the specification originally filed in patent application number 09/894,058 in order to reference the parent and priority applications.

Applicant further notes that the current claims, 1–22, find support in the original Specification as indicated in Table 1, below. Additionally, claims 1, 4, and 22 are modified to bring them into alignment with amendments made during the prosecution of the parent application.

TABLE 1

Current Claim Number	Support in original Specification (i.e. Application No. 09/894,058)
1–5	Original claims 27–31 respectively; original Specification, page 9, lines 1–9
6	Original claim 2
7	Original claim 3
8	Original claim 5
9	Original claim 6
10, 11	Original Specification at page 19, lines 1-6
12	Original claim 9
13	Original claim 13

Current Claim Number	Support in original Specification (i.e. Application No. 09/894,058)
14	Original claim 14
15	Original claim 11
16	Original claim 12
17	Original claim 15
18	Original claim 16
19, 20	Original Specification at page 19, lines 13-15
21	Original claims 16 and 19
22	Original claim 32 and original Specification, page 9, lines 1–9

It is believed that no additional fee is due; however, should any additional fees under 37 C.F.R. §§ 1.16 to 1.21 be required for any reason relating to the enclosed materials, the Commissioner is authorized to deduct said fees from Deposit Account No. 01-2508/11362.0016.DVUS01.

Applicant respectfully submits that the claims are in proper form and condition for allowance. Applicant requests that the claims be allowed and the application advanced to issue.

The Examiner is invited to contact the undersigned Patent Agent at (713) 787-1589 with any questions, comments or suggestions relating to the referenced patent application.

Respectfully submitted,

Matthew Madsen

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